

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION**

ALLIANCE FOR HIPPOCRATIC MEDICINE,	§	
<i>et al.</i> ,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	Case No. 2:22-cv-00223-Z
	§	
U.S. FOOD AND DRUG ADMINISTRATION,	§	
<i>et al.</i> ,	§	
	§	
Defendants.	§	
	§	

**MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
DANCO LABORATORIES, LLC’S UNOPPOSED MOTION FOR LEAVE TO
INTERVENE**

Danco Laboratories, LLC (“Danco”) submits this Memorandum of Points and Authorities in Support of Danco’s Unopposed Motion for Leave to Intervene, pursuant to Rules 24(a) and 24(b) of the Federal Rules of Civil Procedure.

PRELIMINARY STATEMENT

For 22 years, Danco has manufactured and distributed the drug Mifeprex (mifepristone), pursuant to FDA’s approval of the product, having concluded it is safe and effective for its intended use. *See* 2000 FDA Approval Letter for Mifeprex (mifepristone) Tablets at 1 (Sept. 28, 2000), ECF No. 1-26. In this federal case brought by Plaintiffs¹ under the Administrative Procedure Act, 5 U.S.C. §§ 551, 701–706, and the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, Plaintiffs seek to vacate FDA’s initial approval of Mifeprex. They also ask this Court to enjoin the agency to withdraw its supplemental approval of the drug for use in terminating pregnancies in a broader population and under slightly different circumstances. If Plaintiffs secure the relief they seek, Danco will be deprived of the federal agency approval that has guaranteed public access to Mifeprex for more than two decades. Danco has a right to become a party to litigation attacking its own product. *See, e.g., Apotex Inc. v. FDA*, 508 F. Supp. 2d 78, 80 n.2 (D.D.C. 2007) (drug manufacturer permitted to intervene as of right “because the plaintiff seeks to set aside the FDA’s decision as to its approval status”); *Eagle Pharms., Inc. v. Price*, 322 F.R.D. 48, 49–50 (D.D.C. 2017) (manufacturer that had received FDA approval for generic drug product allowed to intervene as of right to “protect its interests”).

¹ Plaintiffs are Alliance for Hippocratic Medicine; American Association of Pro-Life Obstetricians and Gynecologists; American College of Pediatricians; Christian Medical & Dental Associations; Shaun Jester, D.O.; Regina Frost-Clark, M.D.; Tyler, Johnson, D.O.; and George Delgado, M.D. *See* Compl. ¶¶ 33–40, ECF No. 1.

FACTUAL BACKGROUND

In September 2000, FDA approved New Drug Application (NDA) 20-687 for Mifeprex under 21 C.F.R. Part 314, Subpart H, allowing the product to be used in patients who are up to 49 days pregnant. FDA granted Danco's supplemental NDA in 2016, extending access to the drug for patients who are up to 70 days pregnant and lifting other restrictions that the agency determined had no scientific or medical benefit. In 2019, FDA approved a generic equivalent of Mifeprex. And in 2021, facing the COVID-19 pandemic, FDA implemented enforcement discretion regarding the requirement that mifepristone be dispensed in person.

On November 18, 2022, Plaintiffs filed suit in this Court. Their Complaint names as defendants FDA, Robert M. Califf in his official capacity as FDA's current commissioner, and a number of other federal officials (also in their official capacities).² They claim FDA unlawfully approved Mifeprex through the agency's "Subpart H" approval pathway, illegally kept Mifeprex on the market, and unlawfully removed restrictions on the drug's use. Plaintiffs now ask this Court to force FDA to set aside its approval of Mifeprex and its generic equivalent.

ARGUMENT

I. Danco Is Entitled to Intervene As A Matter Of Right Under Rule 24(a).

Rule 24(a) of the Federal Rules of Civil Procedure sets out the requirements for intervention as a matter of right. *See* Fed. R. Civ. P. 24(a)(2); *see also Entergy Gulf States Louisiana, LLC v. EPA*, 817 F.3d 198, 203 (5th Cir. 2016). A party seeking to intervene as of right must make four showings:

- (1) the application for intervention must be timely;
- (2) the applicant must have an interest relating to the property or transaction which is the subject of the action;
- (3) the applicant must be so situated that the disposition of the action may, as a

² Defendants named in the Complaint (the "Federal Defendants") are FDA; Robert M. Califf, M.D.; Janet Woodcock, M.D.; Patrizia Cavazzoni, M.D.; the Department of Health and Human Services; and Xavier Becerra. Compl. ¶¶ 41–46.

practical matter, impair or impede his ability to protect that interest; [and] (4) the applicant's interest must be inadequately represented by the existing parties to the suit.

Entergy, 817 F.3d at 203 (quoting *Haspel & Davis Milling & Planting Co. v. Board of Levee Comm'rs of the Orleans Levee Dist.*, 493 F.3d 570, 578 (5th Cir. 2007)).

Rule 24(a) is framed in mandatory terms that favor intervention. Fed. R. Civ. P. 24(a) (“[T]he court must permit anyone to intervene” who meets the Rule’s requirements). Applying this textual command, the Fifth Circuit liberally construes Rule 24. *Brumfield v. Dodd*, 749 F.3d 339, 341 (5th Cir. 2014) (“Although the movant bears the burden of establishing its right to intervene, Rule 24 is to be liberally construed.”) (citing 6 James W. Moore, et al., *Moore’s Federal Practice* § 24.03[1][a] (3d ed. 2008)). And because “the inquiry under subsection (a)(2) is a flexible one,” courts recognize that “intervention of right must be measured by a practical rather than technical yardstick.” *Edwards v. City of Houston*, 78 F.3d 983, 999 (5th Cir. 1996) (en banc) (courts look to “the particular facts and circumstances surrounding each application” for intervention). Here, the law prescribes one result: Danco should be allowed to intervene.

A. Danco’s Motion To Intervene Is Timely.

Danco easily satisfies Rule 24(a)’s timeliness requirement. Rule 24 does not fix a time within which parties must seek leave to intervene; instead, courts consider whether a motion to intervene is timely by looking to four factors as part of a “contextual” analysis. *Sierra Club v. Espy*, 18 F.3d 1202, 1205 (5th Cir. 1994). First, a court asks how long “the would-be intervenor actually knew,” or should have known, that its interest would not be protected by the existing parties before moving to intervene. *Stallworth v. Monsanto Co.*, 558 F.2d 257, 265 (5th Cir. 1977). A court also considers any prejudice to the existing parties if a would-be intervenor delayed filing its motion (and the motion were granted) as well as prejudice to the potential intervenor (if the

motion were denied). *Id.* at 265–266. Finally, the court evaluates whether any unusual circumstances weigh in favor or against a finding that the motion was timely. *Id.* at 266.

Danco learned of its stake in the action two months ago, when this litigation began, and the Federal Defendants have not yet responded to the complaint. Courts routinely treat motions filed within several months after an intervenor learns of its stake in an action as timely. *See, e.g., Wal-Mart Stores, Inc v. Texas Alcoholic Beverage Comm’n*, 834 F.3d 565, 566 (5th Cir. 2016) (motion to intervene timely when filed three months after defendant filed its answer following denial of motion to dismiss); *NextEra Energy Capital Holdings, Inc. v. D’Andrea*, No. 20-50168, 2022 WL 17492273, at *3 (5th Cir. Dec. 7, 2022) (motion to intervene timely when filed within two months of plaintiffs bringing suit and before defendants filed responsive pleadings); *John Doe No. 1 v. Glickman*, 256 F.3d 371, 375 (5th Cir. 2001) (motion to intervene timely when filed one month after intervenor became aware of its stake in the lawsuit).

Intervention also will not prejudice the existing parties. In *Wal-Mart*, the Fifth Circuit held that because the plaintiff “sought intervention before discovery progressed and because it did not seek to delay or reconsider phases of the litigation that had already concluded,” the motion to intervene was timely. 834 F.3d at 565–566. The same is true here: Danco seeks leave to intervene before the Federal Defendants have responded to Plaintiffs’ preliminary injunction motion, before the Court has entered a case management order, and before any hearing has occurred. By contrast, denying the intervention motion as untimely would prejudice Danco by precluding its participation in a suit seeking to undo its own product’s federal approval.³

³ “The final *Stallworth* factor is the presence of ‘unusual circumstances.’” *Lelsz v. Kavanagh*, 710 F.2d 1040, 1047 (5th Cir. 1983). Unusual circumstances may point toward finding intervention timely where, for example, a dilatory would-be intervenor makes a “convincing” showing “that for reasons other than lack of knowledge he was unable to intervene sooner.” *Jones v. Caddo Par. Sch. Bd.*, 735 F.2d 923, 937 (5th Cir. 1984). Although those circumstances are not present here,

B. Danco Has A Direct Interest Relating To The Action.

When a court determines what counts as an “interest” under Rule 24(a)(2), “[t]he touchstone of the inquiry is whether the interest alleged is ‘legally protectable.’” *New Orleans Pub. Serv., Inc. v. United Gas Pipe Line Co. (NOPSI)*, 732 F.2d 452, 464 (5th Cir. 1984) (en banc). As two different lines of Fifth Circuit precedent show, Danco has a legally protectable interest in this case.

For starters, Danco’s ability to market Mifeprex depends on FDA’s continued approval of the product as safe and effective. As “the ‘intended beneficiary of a government regulatory system,’” Danco “has a legally protected interest in a case challenging that system.” *NextEra*, 2022 WL 17492273, at *3 (quoting *Wal-Mart*, 834 F.3d at 567–569 and citing *Texas v. United States*, 805 F.3d 653, 660 (5th Cir. 2015)). Many people and organizations may harbor a generalized interest in the continued availability of Mifeprex. But as the direct beneficiary of FDA’s 2000 decision, Danco has a unique interest in protecting Mifeprex’s regulatory approval and the privileges that approval confers. This interest, “neither undifferentiated nor generalized,” is sufficient to support intervention. *Texas*, 805 F.3d at 660 (quoting *California ex rel. Lockyer v. United States*, 450 F.3d 436, 441 (9th Cir. 2006) (cleaned up)).

Danco’s economic interests are also directly related to this litigation. Plaintiffs’ lawsuit seeks to undo the very regulatory action permitting Danco to enter the market more than twenty years ago. On that ground, too, Danco maintains a legally protectable interest supporting intervention. *See, e.g., Wal-Mart*, 834 F.3d at 568 (“economic interests can justify intervention when they are directly related to the litigation”) (citing *Espy*, 18 F.3d at 1207); *Black Fire Fighters*

“the lawsuit here is not a traditional private law action but is an example of . . . ‘public law litigation’” featuring what might be described as a ‘structural lawsuit.’” *Id.* (citation omitted). And “[t]he importance of according representation to diverging interests in such a ‘structural’ lawsuit cannot be overemphasized.” *Id.*

Ass'n of Dallas v. City of Dallas, 19 F.3d 992, 994 (5th Cir. 1994) (holding that “prospective interference with [economic] opportunities can justify intervention”). Danco’s ability to provide Mifeprex depends on FDA’s continued approval of the product as safe and effective—an approval Plaintiffs seek to revoke through judicial order. Here, the economic interest at stake is the potential intervenor’s interest in preserving the sole means of lawfully selling its product in this country. It would be impossible to fashion a more directly related economic interest.

C. Disposition Of This Action May Impair Danco’s Ability To Protect Its Interests.

Plaintiffs request relief that cuts to the core of Danco’s proprietary interests. Among other things, Plaintiffs seek to set aside as unlawful FDA’s approval of Mifeprex and ask the Court for an injunction withdrawing the drug’s status as an approved drug. Compl. at 110–111. Danco should be heard on these issues. Were this Court to proceed without Danco’s involvement, the case would be adjudicated in the absence of any input from the party with the most at stake.

That result would be inconsistent with Rule 24. To satisfy Rule 24(a)(2)’s impairment requirement, Danco “need only show that if [it] cannot intervene, there is a possibility that [its] interest could be impaired or impeded.” *La Union del Pueblo Entero v. Abbott*, 29 F.4th 299, 307 (5th Cir. 2022) (citing *Brumfield*, 749 F.3d at 344–345). Based on the allegations in the Complaint and the scope of Plaintiffs’ request for an injunction, there is a risk that this case could work a significant change in Mifeprex’s longstanding regulatory approval. If Mifeprex’s FDA approval were withdrawn as a result of this lawsuit, Danco’s ability to protect its interest in its product would be impeded. And if Danco is not permitted to protect its interests in this litigation, Danco “would be prevented from ever being heard in a lawsuit that has the potential to end” its product’s 22-year regulatory approval. *Glickman*, 256 F.3d at 380.

The risk of impairment to Danco is substantial, all the more so because Plaintiffs seek a “permanent injunction ordering Defendants to withdraw mifepristone” as an FDA-regulated drug. Compl. at 110. Danco therefore satisfies Rule 24(a)(2)’s third requirement.

D. Danco’s Interests Are Not Adequately Represented By Existing Parties.

Finally, for a party to intervene as of right, the “applicant’s interest must be inadequately represented by the existing parties to the suit.” *Entergy*, 817 F.3d at 203. “The applicant has the burden of demonstrating inadequate representation, but this burden is ‘minimal.’” *Id.* (quoting *Brumfield*, 749 F.3d at 345); *see also Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972) (same). The mere possibility that representation “*may* be inadequate” satisfies this requirement for intervention. *Entergy*, 817 F.3d at 203 (emphasis added) (quoting *Haspel*, 493 F.3d at 578).

Danco’s interests are not adequately represented by the Federal Defendants. There are two presumptions of adequate representation; the Federal Defendants satisfy neither. The Federal Defendants are not the “representative of the absentee by law.” *Brumfield*, 749 F.3d at 345. And here, Danco does not have “the same ultimate objective as a party to the lawsuit.” *Id.* (quoting *Edwards*, 78 F.3d at 1005). Danco’s objective is to maintain its regulatory approval and ability to continue providing Mifeprex that can be dispensed to patients who are prescribed it by a provider. As an administrative agency charged with overseeing a vast regulatory apparatus and balancing a wide array of competing demands, FDA’s objectives are quite different. As many drug sponsors can attest, FDA does not—and could not—attempt to protect any one manufacturer’s interest. After all, “[t]he government must represent the broad public interest, not just the economic concerns of the [] industry” it regulates. *Espy*, 18 F.3d at 1208.

FDA has an interest in preserving the independence of its regulatory decision-making processes, ensuring the safety and effectiveness of the products it approves, and enforcing federal law. Danco locates its interests in maintaining the availability of Mifeprex for patients, protecting its product's FDA approval, and safeguarding the company's economic health. As the Fifth Circuit has established, adequacy of representation cannot be inferred simply because the federal government and a would-be intervenor generally agree on a policy. *See Texas*, 805 F.3d at 663 (explaining how the intervenors' interests diverged from the federal government's, even though both supported the immigration policy plaintiffs challenged in the litigation); *see also Entergy*, 817 F.3d at 203 (“[T]he Secretary has an obligation to protect the vital public interest in assuring free and democratic union elections that transcends the narrower interest of the complaining union member.”). Danco's interests are thus not adequately represented by the Federal Defendants.

In sum, Danco meets Rule 24(a)'s requirements to intervene as of right. The Rule's flexible standard points toward mandatory intervention in cases like this one, “where no one would be hurt and the greater justice could be attained.” *Glickman*, 256 F.3d at 375. The Court should grant Danco's motion for leave to intervene.

II. In The Alternative, The Court Should Permit Danco To Intervene Under Rule 24(b).

If the Court finds that Danco does not have a right to intervene under Rule 24(a), the Court in its discretion should allow Danco to intervene under Rule 24(b). Courts may permit intervention where the movant “has a claim or defense that shares with the main action a common question of law or fact.” Fed. R. Civ. P. 24(b)(1)(B). In considering a motion for permissive intervention, the Court considers whether the motion is timely and whether the proposed intervention will “unduly delay or prejudice the adjudication of the rights of the original parties.” Fed. R. Civ. P. 24(b)(3); *see also Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 934 (N.D. Tex. 2019).

Danco's interest in protecting the continued availability of its drug product Mifeprex shares both questions of law and fact in common with this case. Although "[t]imeliness under mandatory intervention is evaluated more leniently than under permissive intervention," *Rotstain v. Mendez*, 986 F.3d 931, 942 (5th Cir. 2021), Danco moves to intervene within weeks of first learning of its interest in the case; the motion is timely for the reasons outlined above. And at this early juncture, Danco's intervention will not delay the litigation or prejudice the rights of either the Plaintiffs or the Federal Defendants. Danco should be permitted to intervene under Rule 24(b).

CONCLUSION

For the foregoing reasons, Danco respectfully requests that this Court grant its Motion for Leave to Intervene.

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Respectfully submitted,

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